June 21, 2021

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
Via PMPRB's online consultation feedback form

Input Regarding PMPRB Proposed Guideline Monitoring and Evaluation Plan

Introduction

The Best Medicines Coalition (BMC), a national alliance of patient organizations together representing millions of patients, welcomes this opportunity to comment on the Patented Medicine Prices Review Board's (PMPRB) proposed Guideline Monitoring and Evaluation Plan (GMEP).

This submission follows input BMC provided in August and February 2020 on draft Guidelines, as well as on proposed reforms, provided in February 2018 and June 2017, and input in October 2016 regarding Health Canada's *PMPRB Guidelines Modernization Discussion Paper*. In addition, BMC has provided input through various correspondence and participation in stakeholder briefing sessions. This submission is based on standing BMC positions and recommendations developed with the participation of BMC member organizations and reflects areas of consensus.

Summary of Positions and Recommendations:

1. BMC continues to support a nuanced position: immediate implementation of the new basket of comparator countries to lower list prices and the delay of the proposed economic factors to allow for extensive review, impact monitoring and evaluation.

2. Significant issues, including the impact of the regulations and concerns about PMPRB processes and impartiality must be resolved, and, therefore, we support action by the government to stay or otherwise cease implementation of the economic factors through Cabinet-approved regulations prior to their planned implementation on July 1, 2021.

3. We recommend the federal government ensure a truly independent evaluation of the impact of its Patent Act regulations by engaging a third-party entity to undertake fulsome consultations with all stakeholders to develop and ultimately implement a monitoring and evaluation regime for the PMPRB-related regulations.

BMC Positions and Recommendations

1. Addressing affordability along with rigourous monitoring and evaluation

BMC continues to support a nuanced position: immediate implementation of the new basket of comparator countries to lower list prices and to call for the delay of the proposed economic factors to allow for extensive review, impact monitoring and evaluation. This long-standing and nuanced position is driven by our patient organization members who are acutely aware that many patients in Canada struggle to pay for some drugs and some patients have unmet needs and wait in hope of new medicines. BMC's positions are informed by these realities and the need to lower prices for patients paying out-of-pocket, and indeed all payers, and ensure that regulations do not have a negative impact on drug introductions and the availability of developer-sponsored clinical trials of investigational drugs in Canada, which help provide early access to promising new therapies.

2. Resolving significant PMPRB process issues

Recent developments have heightened concerns about PMPRB's processes and its willingness and ability to appropriately receive and consider positions expressed by stakeholders, including patient organizations. Specifically, we refer to disturbing allegations regarding patient organizations, including the BMC, expressed in an internal PMPRB Communications Plan obtained through an access to information request by Member of Parliament Tom Kmeic. Furthermore, content and tone put forth in a June 2, 2021 letter to BMC from PMPBR Chair Dr. Mitchell Levine suggest a lack of understanding of our organization's concerns.

BMC's concerns on this matter are detailed in our May 28, 2021 letter to Prime Minister Justin Trudeau and our June 8, 2021 letter to PMPRB Board Chair Dr. Mitchell Levine, provided in response to Dr. Levine's June 2, 2021 letter to the BMC. It is our core belief that the federal government, including the PMPRB, must operate in such a way that diverse concerns, constructive criticisms, and opportunities for improvement, can be expressed and are acknowledged respectfully.

This unfortunate and unacceptable situation has further reinforced our position and highlighted the need to halt full regulatory implementation until significant issues can be reviewed and resolved, including both the impact of the regulations and concerns about PMPRB processes and the duty of PMPRB to be impartial. Specifically, we call on the government to stay or otherwise cease implementation of the economic factors through Cabinet-approved regulations prior to their planned implementation on July 1, 2021.

In addition, we take this opportunity to reiterate specific requests to the PMPRB as stated in BMC's June 8, 2021 letter to Board Chair Dr. Mitchell Levine, as follows:

1. Immediate review by an independent third-party of the PMPRB's current approach to receiving and considering concerns and opposing views on its proposals. We request findings and details on how this situation will be addressed and rectified, including appropriate apologies.
2. Full clarification, including examples of how and where the BMC has disseminated disinformation on access and impact on our patient constituencies, as alleged by PMPRB, and details of alleged aggressive public relations strategies put in place by the BMC, including on social media, and where and when the BMC has engaged in personal attacks.

3. Independent monitoring and evaluation plan prior to implementation

It has been the BMC's long-standing position that there must be full assurance that a rigorous and independent process – outside of PMPRB – will be implemented to monitor, identify, analyze, publicly report, and address any adverse impact on patients' access to medicines and other issues. Furthermore, a plan to execute this must be in place before implementation of the regulations. The lack of an independent evaluation process is another reason for the federal Cabinet to cease implementation of the regulations as is on July 1, 2021.

We request consideration of BMC's previous input on this topic, namely specific recommendations regarding how the PMPRB should approach monitoring and evaluation, in consultation with stakeholders, including the BMC and other patient organizations. Specifically, a section excerpted from BMC August 2020 submission on the Draft guidelines is included as an Appendix.

We stand by the input provided to the PMPRB at that time but yet to be acted upon, as would be evidenced by development of a specific and detailed action plan to monitor and evaluate impact. In the August 2020 submission we provide clear suggestions on what questions the monitoring and evaluation processes must be designed to answer, such as impact on patient access to medications and outcomes, and other critical measures. Note that we also recommended that monitoring and evaluation processes be conducted independent of the PMPRB.

One tangible example of differing points of view which call out for independent resolution is the policy choice whether to focus in PMPRB regulatory performance on the number of drugs licensed by Health Canada versus the number of drugs launched after licensing and sold (actually available to Canadian patients). Health Canada has licensed about 13,000 drug products for human use but only about 8,800 are available and sold. We consider that to be a material difference on drug access/availability for patients.

Recent developments have strengthened our resolve on these recommendations. As we stated in our May 28, 2021 letter to the Prime Minister referenced earlier, given the clear bias and perspective of the PMPRB on the feedback brought forward by patient groups, we do not believe that the PMPRB has the capacity and impartiality to self-monitor and self-evaluate, Furthermore, as we stated in our June 8, 2021 letter to Dr. Levine, we hope that all stakeholders and the PMPRB itself can come together to develop agreed upon research methods and evidence standards, specifically regarding patient access, as part of monitoring and evaluation strategies.

To be clear, BMC believes that PMPRB moving forward to self-monitor and self-evaluate is concerning and inappropriate. Indeed, this could be seen as a conflict of duty or interest. Any monitoring and evaluation regime should be led by a party independent of the PMPRB and without the biases that those within the PMPRB have shown evidence that they hold towards patient organizations such as ourselves.

We recommend the federal government ensure truly independent evaluation of the impact of Its Patent Act regulations by engaging a third-party entity to undertake fulsome consultations with all stakeholders to develop and ultimately implement an evaluation and monitoring regime for the PMPRB-related regulations. Such a pause of PMPRB's current role and initiation of an independent evaluation would be a welcome first step by PMPRB to self-correct its performance and begin to respect its duty to be impartial.

Appendix:

Excerpt: Best Medicines Coalition Input Regarding PMPRB Revised Draft Guidelines
(August 4, 2020)

Comprehensive monitoring, independent evaluation, and adjustments
BMC implores PMPRB and the Government of Canada to provide transparent and comprehensive post-implementation surveillance, including ongoing monitoring and independent evaluation. We request an evaluation process which is broad in scope and rigorous, evaluating the impact on the people of Canada. Building on the areas outlined in the background document provided by PMPRB, we request the incorporation of metrics specifically focussed on patient care outcomes including the availability of new therapeutic options for treating people in Canada in comparison with those in other countries as well as the prices of existing medicines.

Evaluation and monitoring must include both timing and comparisons to other countries and previous medicine launch rates in Canada prior to the application of the new regulations and Guidelines. As an early measure of changes in medicine launches, there must be monitoring of clinical trials, sponsored by drug developers, compared to historical numbers in Canada and other OECD countries. Changes in the number of clinical trials initiated, subjects enrolled, and new medicines researched will be an early sign of the success or shortcomings.

Furthermore, evaluation must include analysis of real savings and subsequent investments, including the health system costs if access to breakthrough medicines is delayed or prevented. Importantly, there must be mechanisms in place to incorporate adjustments within the new framework and Guidelines.

The mechanism and process for monitoring and evaluation, developed in consultation with patient representatives and other stakeholders, should be transparent and conducted regularly with early indicators to trigger early intervention before there is significant harm to Canadians. This must be undertaken in a timely manner with an independent evaluation conducted within 12 to 18 months of implementation and as part of the PMPRB's annual reporting for the first five years following implementation and moving forward. Monitoring and evaluation processes must address these fundamental questions:

- What has been the impact on the range of medicines made available and the timing of introductions, compared to previous levels in Canada and in other countries, on the types of medicines made available and on the number and types of clinical trials conducted in Canada?
- Do the new regulatory framework and Guidelines reduce duplication, improve efficiency, and contribute to health care system sustainability?
- Is the new regulatory framework flexible enough to ensure that new medications to address unmet needs are expedited?
- Do the new regulations ensure that existing and older medicines do not incur price increases that reduce net savings?
- How will patient organizations engage and identify issues and difficulties of accessing breakthrough medicines which may be a direct impact of new regulations?
- Does the new framework contribute to improved patient care and outcomes and, if so, to what extent?
- What is the impact, if any, on drug supplies and shortages?

These monitoring and evaluation processes must encompass high standards of transparency, independence, and accountability, with thorough reporting. Patient communities and other stakeholders should be consulted on design and be involved in implementation and application. Specifically, patients should be part of the team that oversees this process. In addition, an independent audit or independent evaluation would be appropriate to provide Canadians with confidence in our federal pricing regulator.

BEST MEDICINES COALITION
COALITION POUR DE MEILLEURS MÉDICAMENTS

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of patients, with a shared goal of equitable, timely and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities involve issue education, consensus building, planning and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act.

Alliance for Access to Psychiatric Medications
Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Association of Psoriasis Patients
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Psoriasis Network
Canadian Skin Patient Alliance
Canadian Spondylitis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lymphoma Canada
Medical Cannabis Canada
Medicines Access Coalition - BC
Millions Missing Canada
Ovarian Cancer Canada
Parkinson Canada